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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/045,970

01/11/2002

Rami Lidor-Hadas

1662/55602

3018

26646

7590

01/23/2004

KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/045,970	Applicant(s) LIDOR-HADAS ET AL.	
	Examiner Laura L. Stockton, Ph.D.	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 4-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 42-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-47 are pending in the application.

Election/Restrictions

Applicants' election without traverse of Group I in Paper No. 7 was acknowledged in the previous Office Action. The requirement was deemed proper and made FINAL in the previous Office Action.

Claims 4-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen {Zhongguo Yiyao Gongye Zazhi (1993), 24(6), pages 241-242}, Tyers {U.S. Pat. 4,845,115}, Coates et al. {U.S. Pat. 4,695,578} and Tyers {U.S. Pat. 4,835,173}, each taken alone or in combination with each other when similar utilities are asserted. An English translation of Chen was previously provided and will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim Ondansetron hydrochloride dihydrate. Each of Chen {page 1, Compound (1) and page 2- section III}, Tyers '115 {column 3 and especially Example 2 in column 3}, Coates et al. {column 4 and especially Example 10 in column 20} and Tyers '173 {column 3 and especially Example 2 in column 3} teach Ondansetron hydrochloride dihydrate.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claimed invention and the prior art is that the prior art is silent as to the purity of the product obtained.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

Changing the form, purity, color, or other characteristic of an old product without a new use as a result thereof does not render product patentable where utility remains the same. Ex parte Hartop, 139 USPQ 525. Therefore, absent a showing of a viable unexpected, unobvious and superior properties, the instant claimed compound would have been suggested to one skilled in the art.

Response to Arguments

Applicants' arguments filed October 10, 2003 have been fully considered. Applicants argue that: (1) none of the cited prior art disclose exo-methylene by-products in relation to ondansetron; (2) none

of the cite prior art suggests or teaches a method of removing the exo-methylene by-products; and (3) a compound in a purer or modified form may, if unobvious in that form, be patentable over the same compound as it existed in the prior art but claims thereto must be limited so as to exclude from the scope thereof the compound as it existed in the prior art. Applicants also cite Ex parte Hillyer et al. 102 USPQ 126 (POBA 1953); In re Kebrich 96 USPQ 41 1 (CCPA 1953); and Ex parte Frohardt et al. 139 (USPQ 377 (POBA 1962)).

All of Applicants' arguments have been considered and the cases cited reviewed. Applicants argue that none of the cited prior art disclose exo-methylene by-products in relation to ondansetron. In response, each of the prior art teach methods for improving the purity of Ondansetron hydrochloride dihydrate by recrystallization and thereby removing any by-products such as exo-methylene by-products. Note the specified sections of the prior art indicated above.

Applicants argue that a compound in a purer or modified form may, if unobvious in that form, be patentable over the same compound

as it existed in the prior art but claims thereto must be limited so as to exclude from the scope thereof the compound as it existed in the prior art. In response, Applicants claim Ondansetron hydrochloride dihydrate. Each of Chen {page 2- section III}, Tyers '115 {Example 2 in column 3}, Coates et al. {Example 10 in column 20} and Tyers '173 {Example 2 in column 3} teach Ondansetron hydrochloride dihydrate. The difference between the instant claimed invention and the prior art is that the prior art is silent as to the purity of the product obtained. Unlike in Ex parte Hillyer et al., In re Kebrich, and Ex parte Frohardt et al., all cited by Applicants, Applicants' compounds are of the same identical formula and are used for the same purposes as known in the prior art. Therefore, absent a showing of a viable unexpected, unobvious and superior properties, the instant claimed compound would have been suggested to one skilled in the art. Therefore, the rejection is deemed proper and is maintained.

Conclusion

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to

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Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

January 20, 2004